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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/002,933	11/01/2001	Jeong S. Lee	ACSC 60355 (2750)	5440
7590 12/16/2004		EXAMINER		
GUNTHER O. HANKE, ESQ. FULWIDER PATTON LEE & UTECH, LLP HOWARD HUGHES CENTER 6060 CENTER DRIVE, TENTH FLOOR LOS ANGLES, CA 90045			MCKANE, ELIZABETH L	
			ART UNIT	PAPER NUMBER
			1744	· · · · · · · · · · · · · · · · · · ·

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
Office Action Summary		10/002,933	LEE ET/AL.				
		Examiner	Art Unit				
		Leigh McKane	1744				
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status							
1)[Responsive to communication(s) filed on 19 October 2004.						
2a)⊠		is action is non-final.					
3)	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Dispositi	on of Claims						
4) 🖾	☑ Claim(s) <u>1-3,5,7-12,14-24 and 26-35</u> is/are pending in the application.						
•	4a) Of the above claim(s) is/are withdrawn from consideration.						
5)🛛	Claim(s) <u>1-3,5,7-12,14-23 and 27-35</u> is/are allowed.						
6)⊠	6)⊠ Claim(s) <u>24 and 26</u> is/are rejected.						
7)	Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement. Application Papers							
9) The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12)☐ The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the codified expires not received.							
* See the attached detailed Office action for a list of the certified copies not received.							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
 a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. 							
Attachment	(s)	•					
2) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10</u>	5) Notice of Informal P	(PTO-413) Paper No(s) Patent Application (PTO-152)				

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Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the

manner in which the invention was made.

2. Claims 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et

al (U.S. Patent No. 5,849,846) in view of Sun et al (U.S. Patent No. 5,728,748).

Chen et al teaches a method of sterilizing a medical device component wherein the

component (e.g. dilation catheter tubing material for balloons and catheters) is irradiated with an

electron beam (col.9, lines 21-45) to improve the performance characteristics of the component.

Chen et al is silent as to whether the e-beam radiation sterilizes the component. However, Sun et

al teaches that e-beam radiation at a dose of 2.5 Mrad is effective in sterilizing polymeric

materials. As the component of Chen et al will have to eventually undergo sterilization before

use and since it is fabricated from a polymeric material like the components of Sun et al, one of

ordinary skill in the art would have found it obvious to use the e-beam sterilization of Chen et al

to both improve the performance characteristics of the component and to sterilize the component.

As the combination of Chen et al with Sun et al teaches a sterilized medical device

(balloon catheter), the product-by-process claims 24 and 26 are rendered obvious.

Allowable Subject Matter

3. Claims 1-3, 5, 7-12, 14-23, 27-35 are allowed.

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Response to Arguments

- 4. Applicant's arguments, filed 19 October 2004, with respect to claims 1-3, 5, 7-12, 14-23 and 27-35 have been fully considered and are persuasive. The rejection of these claims has been withdrawn.
- 5. Applicant's arguments filed 19 October 2004, with respect to claims 24 and 26 have been fully considered but they are not persuasive.

It has not been shown that the medical device/balloon catheter sterilized by the methods of claims 24 and 26 is any different that that sterilized by the combination of Chen et al with Sun et al.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Wednesday (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1275. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Leigh McKane

Primary Examiner

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elm

13 December 2004